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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/075,970  | 02/14/2002  | Michael Helmus       | 01-202              | 9278             |
| 27774   | 7590        | 12/13/2005           | EXAMINER            |                  |
| MAYER, FORTKORT & WILLIAMS, PC<br>251 NORTH AVENUE WEST<br>2ND FLOOR<br>WESTFIELD, NJ 07090 |             |                      | HO, UYEN T          |                  |
|   |             |                      | ART UNIT            | PAPER NUMBER     |
|   |             |                      | 3731                |                  |

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                     |                                 |  |
|------------------------------|-------------------------------------|---------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/075,970       | Applicant(s)<br>HELMUS, MICHAEL |  |
|                              | Examiner<br>(Jackie) Tan-Uyen T. Ho | Art Unit<br>3731                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.  
 2a) ☒ This action is FINAL.                      2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-45 is/are pending in the application.  
     4a) Of the above claim(s) 22-44 is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1,3-21, 45 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments and the amendment filed 9/28/05 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 3-21, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Datta et al. (6,338,739). Datta et al. disclose a stent comprising a biodegradable inner core and a biodegradable outer covering material wherein after insertion into a patient, the stent becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time. Although, Datta et al.'s stent is made from polymeric material, it would have been obvious matter of design choice to modify the Datta et al.'s stent by making the stent from the materials as claimed, a biodegradable hydrogel, metallic or ceramic material since the applicant has not disclosed that the stent made from a biodegradable hydrogel, metallic or ceramic material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Applicant's invention to perform equally well with Datta et al.'s stent because the inner core being made from

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biodegradable polymer or metal or ceramic material would perform equally well such that the stent would decrease rigid or become more flexible and increasingly biomechanically compatible.

4. Claims 1, 3-21, 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (WO98/56312). Wang et al. disclose a stent comprising a biodegradable inner core and a biodegradable outer covering material wherein after insertion into a patient, the stent becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time. Although, Wang et al.'s stent is made from polymeric material, it would have been obvious matter of design choice to modify the Wang et al.'s stent by making the stent from the material as claimed, a biodegradable hydrogel, metallic or ceramic material since the applicant has not disclosed that the stent made from a biodegradable hydrogel, metallic or ceramic material provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Applicant's invention to perform equally well with Wang et al.'s stent because the inner core being made from biodegradable polymer or metal or ceramic material would perform equally well such that the stent would decrease rigid or become more flexible and increasingly biomechanically compatible.

***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is 571-272-4696. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANHTUAN NGUYEN can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



(Jackie) Tan-Uyen T. Ho  
Patent Examiner  
Art Unit 3731

December 5, 2005